2. Medical Education Seminars

103. Upon information and belief, kickbacks to physicians to hear promotions of Neurontin for unapproved uses took another form in programs billed as Continuing Medical Education seminars ("CME").

104. These conferences and seminars were set up to appear to qualify for an exception to the FDA's marketing restrictions regarding unapproved uses, which permit physicians to learn about unapproved uses of pharmaceuticals at independent seminars.

105. Pharmaceutical companies may make "unrestricted grants" for the purpose of a seminar, but may not be involved in formulating the content of the presentations, selecting the speakers or selecting the attendees.

106. Upon information and belief, these requirements were, in large part, ignored with regard to the CME seminars sponsored by Warner-Lambert for the promotion of unapproved uses of Neurontin.

107. Warner-Lambert designed and approved the programs; hand-picked the speakers for the seminars; approved the seminar presentations of the seminars; previewed, in most cases, the contents of the seminars prior to delivery; selected the attendees based on their ability and willingness to prescribe high quantities of Neurontin; evaluated the presentations to make sure Parke-Davis's "message" was appropriately delivered; black-listed presenters whose presentations were not sufficiently pro-Neurontin; and monitored the prescribing patterns of the physicians who attended these conferences to insure the purpose of the conference – increased writing of Neurontin prescriptions – was achieved.

108. Follow-up reports to marketing executives at Warner-Lambert highlighted that the attendees received presentations regarding unapproved uses and recommendations for dosages larger than those labeled effective by the FDA.

109. These memoranda also reported to senior executives the pledges made by attendees to order more Neurontin for their patients.

110. For some seminars, high prescription writing physicians were selected to receive junkets comparable to those Warner-Lambert provided to the attendees of the Jupiter Beach "consultants" meetings.

111. Frequently, the Warner-Lambert CME seminars were accredited by continuing medical education organizations, which meant that the physicians taking advantage of Warner-Lambert junkets did not have to pay tuition or spend additional time to fulfill their continuing medical education licensure requirements.

112. Representative CME programs sponsored by Warner-Lambert included, but are not limited to, the following:

Merritt-Putnam Epilepsy Postgraduate Course, January 19, 1996
Merritt-Putnam Seminar, Chicago, IL January 26, 1996
New Frontiers in AntiEpileptic Drug Use, California Sept-Oct 1996
Diabetic Neuropathy Ritz Carlton, Boston, MA June 22-24, 1997
Merritt-Putnam Symposium Key Biscayne, FL September 11, 1997
Merritt-Putnam Conference on Monotherapy, Palm Springs, CA September 9, 1997
Merritt-Putnam Conference on Monotherapy, St. Louis, MO October 3, 1997
Merritt-Putnam Symposium Boston, MA December 5, 1997

3. Grants and "Studies"

113. Upon information and belief, Warner-Lambert also made outright payments, in the form of "grants", to reward demonstrated Neurontin believers and advocates.

114. Upon information and belief, Warner-Lambert sales managers identified key physicians who actively prescribed Neurontin or programs which were willing to host Neurontin speakers and encouraged such persons or programs to obtain "educational grants" from Warner-Lambert. Under this program of so-called "grants," Warner-Lambert, upon information and belief, paid thousands of dollars in kickbacks to selected physicians.

115. Upon information and belief, these grants, and others, were charged to the Neurontin marketing budget.

116. Upon information and belief, these grants were generally made to individuals who were Neurontin supporters or hosts of programs where well-known Neurontin supporters would recommend that other physicians increase their prescriptions of Neurontin. Upon information and belief, such grants constituted a reward or kickback for the recipient's advocacy of Neurontin.

117. Upon information and belief, Warner-Lambert's medical liaisons made it known to leading Neurontin subscribers that significant advocacy for Neurontin would result in the payment of large grants.

118. Upon information and belief, the studies often required little more than collating and writing up office notes or records. Indeed, Warner-Lambert frequently hired technical writers to write the articles for which the "authors" had been given grants.

119. Upon information and belief, Warner-Lambert was aware, or should have been aware, that these articles and studies provided minimal scientific benefit.

120. In a letter to the FDA in June 1997, Warner-Lambert submitted a list of "studies relating to pain, pain syndromes, and psychiatric disorders" which failed to

include any of these numerous studies, purportedly funded by Warner-Lambert. Upon information and belief, Warner-Lambert did not report these "studies" to the FDA because the funded "research" had little scientific value and would not have been credited by the FDA.

121. Payments Parke-Davis made for "studies" included, but were not limited to the following:

Statistical Analysis of Patients Treated With Neurontin For Pain, Hans Hansen, M.D.; Statesville, NC $7,000.00
Reduction of Sympathetically Medicated Pain and Sudomotor Function, David R. Longmire, M.D.; Russellville, AL $7,000.00
Data entry for Neurontin and Pain Analysis, Travis Jackson, M.D., David Meyer, M.D.; Winston-Salem, NC
Trial of Neurontin for distal symmetric polyneuropathy associated with AIDS, Joseph Weissman, M.D. Atlanta, GA $20,000.00
Neurontin for neuropathic pain in chronic pain syndromes, Lavern Brett, M.D., Washington, D.C., $25,000.00
Retrospective chart analysis of Neurontin use with bipolar disorder patients, Ralph S. Rybeck, M.D. $5,000.00
Retrospective Analysis of Neurontin in the treatment of pain, David R. Longmire, M.D.; Russellville, AL, $2,000.00
Retrospective Analysis of Neurontin in the treatment of chronic pain, Don Schanz, D.O., Traverse City, MI, $8,000.00
Case histories relating to use of Neurontin as an adjuvant analgesic, Elizabeth J. Narcessian, M.D; W. Orange, NJ, $4,000.00

122. Upon information and belief, other payments were made to physicians for other "studies" of questionable scientific credibility and value.

123. One particularly large study conducted by Warner-Lambert served as yet another means to financially reward physicians for prescribing Neurontin.

124. In 1995 and 1996, Warner-Lambert conducted an enormous Phase IV trial known as STEPS. Although STEPS took the form of a research clinical trial, it was, upon information and belief, a marketing ploy designed to induce neurologists to become

comfortable prescribing Neurontin at a far higher dose than indicated in the FDA approved labeling.

125. While most clinical studies have a limited number of investigators treating a number of patients qualified for the study, the STEPS protocol called for over 1,200 "investigators" to enroll only a few patients each.

126. Upon information and belief, the participating physicians were instructed to titrate their patients to higher than labeled dosages of Neurontin to demonstrate that patients could tolerate high dosages of the drug.

127. Upon information and belief, rewarding physicians for prescribing high doses on Neurontin was another way to increase Neurontin sales because higher per patient dosages increased the amount of Neurontin sold.

128. Additionally, the STEPS study was also designed, upon information and belief, to habituate physicians to place non-study patients on Neurontin on doses higher than found effective in the clinical trials monitored by the FDA.

129. Physicians enrolling in the STEPS study were paid for agreeing to participate in the study and for every patient enrolled.

130. At the conclusion of the study, Warner-Lambert, upon information and belief, offered each of the 1,200 "investigators" additional cash for each patient the physician kept on Neurontin after the study ended.

131. These payments appear to be kickbacks, because each participating physician was paid for writing Neurontin prescriptions for their patients. The number of "investigators" who received such payments appear to be two voluminous.

132. Additionally, Warner-Lambert had exclusive control of the information regarding who received such payments at the conclusion of the STEPS trial.

4. Payments to "Authors" of Ghost Written Articles

133. Another method of rewarding physicians for their advocacy of Neurontin was to pay them honorarium for lending their names to scientific articles which were actually prepared and written by third parties retained by Warner-Lambert.

134. In 1996, Warner-Lambert retained AMM/ADELPHI, Ltd. and Medical Education Systems, Inc., to prepare no less than twenty (20) articles for publication in various neurology and psychiatry journals. Many of these articles concerned unapproved uses of Neurontin.

135. The content of these articles was often written by non-physician technical writers retained by Warner-Lambert. Upon information and belief, Warner-Lambert had the right to control the content of the articles. Warner-Lambert paid expenses in connection with the creation of these publications.

136. Upon information and belief, once Warner-Lambert and the technical writers conceived the articles, Warner-Lambert and its outside firms attempted to find recognized Neurontin prescribers whose names could be used as the authors of these articles. In some cases, drafts of the articles were completed even before an "author" agreed to place his or her name on the article.

137. Upon information and belief, the "authors" were paid an honorarium of $1,000.00 to lend their names to these articles, and also were able to claim publication credit on their curriculum vitae.

138. After the technical writers completed their work, Warner-Lambert and its outside firms found journals that would publish the articles. Warner-Lambert's role in creating, approving and sponsoring the articles was not revealed to the reader.

139. The articles at times reference that the author received an honorarium, but that was paid with money provided by Warner-Lambert and that Warner-Lambert had approved the content and

hired the actual authors.

140. For example, an article created by Medical Education Systems (MES), *Gabapentin and Lamotrignine: Novel Treatments for Mood and Anxiety Disorders,* published in CNS Spectrums noted that "an honorarium was received from Medical Education Systems for preparation of this article," but never revealed Warner-Lambert's retention and payment of MES or the fact that MES personnel, while under contract to Warner-Lambert, wrote the article.

141. Upon information and belief, Warner-Lambert used these publications as part of a "publication strategy" by presenting the articles as evidence of independent research conducted by persons with no monetary interest in Neurontin.

142. Upon information and belief, the impression purposely conveyed to the medical industry and consumers was false. Warner-Lambert created the articles to promote unapproved uses for Neurontin, purchased the names and reputations of the authors with kickbacks and controlled the content of the articles.

5. Speakers' Bureau

143. Warner-Lambert utilized the "Speakers' Bureau" as another method to make numerous payments to physicians who recommended Neurontin at teleconferences, dinner meetings, consultants meetings, educational seminars, and other events.

144. Upon information and belief, these speakers gave short presentations relating to Neurontin for which they were paid anywhere from $250.00 to $3,000.00 per event.

145. Upon information and belief, speakers received payments after recommending to fellow physicians that Neurontin be prescribed, particularly for unapproved uses.

146. Upon information and belief, speakers who most zealously advocated Neurontin were hired most frequently for speaking events, notwithstanding the fact that many of these events purported to be independent medical education seminars where independent information was supposed to be delivered.

147. Upon information and belief, Warner-Lamber's marketing personnel, including its medical liaison staff, informed physicians of the lucrative rewards of joining the Neurontin Speaker's Bureau. Upon information and belief, physicians were informed that if they prescribed enough Neurontin, they, too, could also be eligible for receiving substantial payments just for describing their clinical experience to peers at events dedicated to promoting Neurontin's unapproved uses.

148. Upon information and belief, it was made clear that the way to receive such payments was to prescribe substantial amounts of Neurontin.

149. In taking the foregoing actions, Warner-Lambert either knew that the payments described above constituted kickbacks or acted in reckless disregard of laws and regulations of which it was aware. For instance, Warner-Lambert was well aware of the Medicare and Medicaid Fraud and Abuse laws, which included the Medicaid antikickback statute.

150. Upon information and belief, Warner-Lambert was further aware that the safe harbors established by the Department of Health and Human Services did not cover the extensive payments it made to physicians. Upon information and belief, Parke-Davis was aware that its payments did not comply with the AMA's guidelines for payments to physicians.

151. Upon information and belief, Warner-Lambert was also aware of the Inspector General's Special Fraud Alert which raised particular concerns about drug marketing.

152. In 1997, in the wake of an investigation by the FDA, Warner-Lambert conducted a review of its marketing practices in light of existing Medicaid kickback regulations.

153. As a result of that review, Warner-Lambert determined that none of the programs described above should have been conducted in the manner previously conducted by Warner-Lambert.

154. Warner-Lambert issued guidelines to comply with Federal Regulations which essentially prohibited each of the programs described above.

6. Medical Liaisons

155. By law, Warner Lambert's normal sales force was not permitted to promote "off- label" uses of Neurontin to its physician customers.

156. The FDA, however, permitted drug company representatives to provide balanced, truthful information regarding unapproved usage if specifically requested by a physician and if there was no attempt to solicit such information by the drug company.

157. Commencing in 1995, Warner-Lambert increasingly hired medical liaisons and trained them to aggressively solicit requests for information regarding unapproved uses from physicians.

158. Upon information and belief, Warner-Lambert then trained the medical liaisons to engage in full-scale promotion of Neurontin's unapproved uses, including repetitive distribution of non-scientific, anecdotal information designed to convince physicians that unapproved uses of Neurontin were safe and effective.

159. In effect, Warner-Lambert used the medical liaisons as a surrogate sales force who had liberty to solicit physicians regarding unapproved uses. Indeed, medical liaisons were selected and promoted based on their ability to sell and sales training was encouraged.

160. Upon information and belief, on April 16, 1996, at a training session for medical liaisons, Warner-Lambert in-house lawyers stopped the video taping of a medical liaison training session to advise the liaisons that notwithstanding formal policies to the contrary, liaisons could cold call on physicians so long as they had executed request

forms (forms that supposedly verified that the physician had initiated the meeting) at the end of the call.

161. Upon information and belief, moreover, the liaisons were informed that the request forms could be filled out by Warner-Lambert sales representatives instead of the physicians.

162. Upon information and belief, the liaisons in training, were informed that there was no need to present balanced information to the customers and that liaisons should always remember that sales were necessary in order to keep the company profitable.

163. Upon information and belief, the liaisons were also informed that there really was no definition of "solicitation" and that there were methods to induce the physicians to inquire about unapproved uses. In effect, once the medical liaison got a meeting with a physician, there were ways to get the information about unapproved uses to the physician even if the physician had not requested information about any unapproved uses.

164. Upon information and belief, the liaisons were advised not to put information about unapproved uses in writing.

165. Upon information and belief, it became clear to liaisons that they were to market and sell Neurontin based on its unapproved uses. On a teleconference on May 24, 1996, for instance, a marketing executive at Warner-Lambert's Morris Plains headquarters informed the medical liaisons that in order to market Neurontin effectively, Neurontin had to be marketed for monotherapy, pain, bipolar disorder, and other psychiatric uses, all of which were unapproved uses at the time.

166. Upon information and belief, the executive conceded that such marketing had to be primarily performed by the medical liaisons, because they were the only ones who could discuss these matters. At another meeting with the medical liaisons, the executive was even more blunt:

> "I want you out there every day selling Neurontin. Look this isn't just me, it's come down from Morris Plains that Neurontin is more profitable. . . . We all know Neurontin's not growing adjunctive therapy, beside that is not where the money is. Pain management, now that's money. Monotherapy, that's money. We don't want to share these patients with everybody, we want them on Neurontin only. We want their whole drug budget, not a quarter, not half, the whole thing . . . .We can't wait for them to ask, we need to get out there and tell them up front. . . .That's where we need to be holding their hand and whispering in their ear Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything . . . I don't want to see a single patient coming off Neurontin until they have been up to at least 4800 mg/day. I don't want to hear that safety crap either, have you tried Neurontin, every one of you should take one just to see there is nothing, it's a great drug."

167. Thus, medical liaisons were trained to cold call high decile physicians (those who saw the most patients in a given specialty), and sell them on the benefits of the unapproved uses of Neurontin.

168. Upon information and belief, in or about May 1996, a Warner-Lambert medical director based in the northeast CBU sent a voicemail message to the medical liaisons in the northeast CBU in which he stated:

> What we'd like you to do is, any time you're called out just make sure that your main focus of what you're doing is on Neurontin … When we get out there, we want to kick some ass, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that's what we want to do.

Upon information and belief, medical liaisons in the northeast CBU interpreted this statement to mean that they should promote Neurontin for unapproved uses and,

thereafter, in or about May and June 1996, promoted Neurontin for neuropathic pain, an unapproved use.

169. Upon information and belief, Warner-Lambert employed "medical liaisons" who were presented to physicians as employees of the company's medical and scientific affairs department. Upon information and belief, these liaisons promoted unapproved uses of Neurontin.

170. Upon information and belief, the following misrepresentations relating to unapproved uses of Neurontin were made to physicians with the knowledge and consent of marketing personnel at Warner-Lambert:

> 1. *Bipolar Disorder*. Medical liaisons informed psychiatrists that early results from clinical trials evaluating Neurontin for the treatment of bipolar disorder indicated a ninety percent (90%) response rate when Neurontin was started at 900 mg/day dosage and increased to a dosage of 4800 mg/day. No such results existed. Nor was any type of clinical trial being conducted other than a pilot study. There were no clinical trials or studies indicating that Neurontin was safe or effective up to 4800 mg/day. Indeed, Parke-Davis was in possession at this time of clinical trial evidence which showed that there was no dose response difference between patients who received 600 mg/day, 1200 mg/day and 2400 mg/day. Any data relating to the use of Neurontin in bipolar disorder was strictly anecdotal and of nominal scientific value. Indeed, most of the published reports on this topic had been written and commercially sponsored by Parke-Davis, although this fact was hidden. Medical liaisons were trained to inform psychiatrists that there were 110 reports of adverse effects for Neurontin when used for psychiatric purposes. In fact, such reports had been reported to Parke-Davis personnel, but Parke-Davis attempted to hide such reports from physicians.
> 2. *Peripheral Neuropathy, Diabetic Neuropathy, and Other Pain Syndromes*. Medical liaisons were trained and instructed to report that "leaks" from clinical trials demonstrated that Neurontin was highly effective in the treatment of various pain syndromes and that a ninety percent (90%) response rate in the treatment of pain was being reported. No such body of evidence existed. Nor was there any legitimate pool of data from which a response rate, much less a ninety percent (90%) response rate, could be calculated. Medical liaisons were trained to claim support for these findings as a result of inside information about clinical

trials where no such information existed. The only support for these claims was anecdotal evidence of nominal scientific value. Many of the published case reports had been created and/or sponsored by Parke-Davis in articles which frequently hid Parke-Davis's involvement in the creation of the article. Parke-Davis's payment for the creation of these case reports was also hidden from physicians.

3. *Epilepsy Monotherapy*. Medical liaisons were strongly encouraged to push neurologists to prescribe Neurontin as the sole medication to treat epilepsy, even though studies only found it safe and effective as adjunctive therapy. Medical liaisons were trained to inform neurologists that substantial evidence supported Parke-Davis's claim that Neurontin was effective as monotherapy. In fact, at this time, Parke-Davis knew that clinical trials regarding Neurontin's efficacy as a monotherapy were inconclusive. One of Parke-Davis's clinical trials, 945-82, demonstrated that Neurontin was not an effective monotherapy agent; the vast majority of patients in the study taking Neurontin were unable to continue with Neurontin alone. The same study showed that there was no effective difference between administration of Neurontin at 600, 1200 or 2400 mg. Notwithstanding this data, the Parke-Davis continued to claim that physicians should use Neurontin at substantially higher doses than indicated by the labeling. Indeed, although medical liaisons routinely claimed Neurontin to be effective as monotherapy, in 1997 the Food and Drug Administration refused to find Neurontin a safe and effective monotherapy.

4. *Reflex Sympathetic Dystrophy ("RSD")*. Medical liaisons informed physicians that extensive evidence demonstrated the efficacy of Neurontin in the treatment of RSD. The only such evidence that existed was anecdotal reports of nominal scientific value. Medical liaisons were trained to refer to case reports, most of which had been created or sponsored by Parke-Davis, as "studies."

5. *Attention Deficit Disorder ("ADD")*. Medical liaisons were instructed to inform pediatricians that Neurontin was effective for the treatment of ADD. No data, other than occasional anecdotal evidence, supported this claim. Nonetheless, the medical liaisons were trained to report that large number of physicians had success treating ADD with Neurontin, when no such case reports existed.

6. *Restless Leg Syndrome ("RLS")*. RLS was another condition where Parke-Davis's medical liaisons were trained to refer to a growing body of data relating to the condition, when no scientific data existed. The only reports were anecdotal, most of which had been created and/or sponsored by Parke-Davis.

7. *Trigeminal Neuralgia*. Although medical liaisons represented that Neurontin could treat Trigeminal Neuralgia, again no scientific data supported this claim with the exception of occasional anecdotal reports. No data demonstrated that Neurontin was as effective as currently available pain killers, most of which were inexpensive.

8. *Post-Herpatic Neuralgia ("PHN")*. Medical liaisons were trained to tell physicians that seventy-five percent (75%) to eighty percent (80%) of all PHN patients were successfully treated with Neurontin. Once again, no clinical trial data supported such a claim.
9. *Essential Tremor Periodic Limb Movement Disorder ("ETPLMD")*. Medical liaisons were trained to allege that Neurontin was effective in the treatment of these conditions. No scientific data supported such claims with the exception of anecdotal reports of nominal scientific value.
10. *Migraine*. Claims that Neurontin was effective in the treatment of migraine headaches were made by the medical liaisons and were supposedly based on early results from clinical trials. Although pilot studies had been suggested and undertaken, no early results of clinical trials existed to support these claims. Once again, any data relating to treatment of migraines was purely anecdotal and of nominal scientific value. Most of the case reports were either created or sponsored by Parke-Davis.
11. *Drug* and *Alcohol Withdrawal Seizures*. Medical liaisons suggested that Neurontin be used in the treatment of drug and alcohol withdrawals despite the lack of any data supporting Neurontin as an effective treatment for these conditions.

171. Upon information and belief, Warner-Lambert's medical liaisons were instructed to make exaggerated or false claims concerning the safety and efficacy of Warner-Lambert drugs for unapproved uses.

172. Upon information and belief, the medical liaisons were also trained to convey that Neurontin could be

prescribed for its various unapproved uses in amounts of up to 4800 mg/day — far above the maximum dosage of 1800 mg per day approved by the FDA.

F. The Whistleblower Action Uncovers Criminal Conduct

173. At some point, questions arose concerning the availability of reimbursement for prescriptions for unapproved uses of Warner-Lambert drugs. Upon information and belief, in response, Warner-Lambert's medical liaisons were instructed to coach physicians on how to conceal the fact that the prescription was one for an unapproved use.

174. Upon information and belief, Warner-Lambert took numerous other unfair and deceptive actions to conceal its activities from the FDA and consumers, including shredding documents, falsifying documents, and encouraging medical liaisons to conduct their marketing activities without leaving a "paper trail" that might be discovered.

175. Dr. Paul Franklin brought a whistleblower action that eventually led Warner-Lambert to admit guilt to criminal charges. Among other things, those allegations included the following:

- Upon order of the company and as a result of training of medical liaisons, Dr. Franklin of Parke-Davis "deliberately contrived reports to mislead physicians into believing that a body of data existed that demonstrated the effectiveness of Neurontin in the treatment of bipolar disease." In fact, no data existed at all to support the use of Neurontin in bipolar disorder.
- Dr. Franklin was trained and instructed to actively deceive physicians with contrived data, falsified "leaks" from clinical trials, scientifically flawed reports, or "success stories" that stated that Neurontin was highly effective in the treatment of a variety of pain syndromes. No such body of evidence existed.
- He was instructed to advise physicians that Parke-Davis had developed a large body of data to support the use of Neurontin as monotherapy. This was an "outright lie" and left patients unknowingly without good seizure control.
- Medical liaisons were instructed to tell physicians that a great deal of data existed that supported the safe use of Neurontin at levels that exceed 4800 mg/day. However, clinically significant safety data existed at dosing levels at only 1800 mg/day.
- Parke-Davis provided medical liaisons with slides that stated that Neurontin was effective for the treatment of Attention Deficit Disorders but no data existed to support that claim.

176. By all indications, Defendants' strategy for illegal marketing of Neurontin was a complete success. In 2000, Warner-Lambert reported that more than 78% of Neurontin prescriptions had been written for indications other than epilepsy.

177. According to IMS Health (news/quote), a health care information company, sales of Neurontin that year were $1.3 billion, and they rose to $1.7 billon.

178. The unapproved uses of Neurontin which were actively being promoted by Warner-Lambert were uses which were not recognized as medically accepted uses by the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, or the American Medical Association Drug Evaluations, or by any peer-reviewed medical literature.

179. Thus, these unapproved uses are beyond the scope of uses designated by federal law and regulation, in particular 42 U.S.C. § 1396r-8, as eligible coverage by the Medicare and Medicaid programs.

180. Federal laws and regulations governing the Medicare and Medicaid programs prohibit kickbacks to physicians and medical care providers, in particular 42 U.S.C. § 1320A-7 and 42 C.F.R. § 1001.

181. "Kickbacks" have been defined as including payments, gratuities, and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

182. As part of its program of promoting Neurontin for unapproved uses, Warner-Lambert established a system of kickbacks to physicians who are prescribers of large amounts of Neurontin.

183. These kickbacks were administered by the Defendants' sales departments and deceptively disguised as consultantships despite the fact that they were unrelated to legitimate scientific or educational activity.

184. The kickbacks took the form of cash payments, travel benefits, entertainment, Olympics tickets, and other benefits.

185. Upon information and belief, Warner-Lambert established formal internal guidelines for the award of these benefits to physicians which are based entirely on the amount of prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing Neurontin for unapproved uses.

186. These kickbacks are illegal and have had the effect of greatly increasing the amount of Neurontin prescriptions and the amount of money spent by the federal government for reimbursement of prescriptions covered by Medicare and by consumers.

187. The payment of these kickbacks represents the inducement of federal payments through a pattern of fraudulent conduct and constitutes False Claims within the meaning of 31 U.S.C. § 3729.

V. Causes of Action

COUNT I
(Mrs. Dorsey v. All Defendants)
(Massachusetts Consumer Protection Statute, G.L. c. 93A §§ 2, 9 *et seq.*)

188. The preceding paragraphs of this Complaint are realleged and incorporated by reference as if fully set forth herein.

189. G.L. c. 93A § § 2, 9 make it unlawful for businesses to utilize false, deceptive or unfair business practices, including but not limited to false and deceptive advertising and promoting the use of unsafe products.

190. As a result of the violations of Massachusetts and federal law described herein, Defendants have used unfair and deceptive trade practices, including false and misleading advertising, to unjustly enrich themselves at the expense of Plaintiff and the general public.

191. On or about January 13, 2005, Plaintiff's counsel forwarded a demand letter to Defendants conforming to the requirements of Mass. Gen. L., c. 93A, §§ 2, 9.

192. The demand letter was received by Defendants at least thirty days prior to filing this action, identified the claimants herein, reasonably described the unfair and deceptive acts or practices engaged in by Defendants, and provided notice that a claim under G.L. c. 93A was being asserted by Plaintiff.

193. Defendants' response to the demand letter, dated February 14, 2005, was unreasonable and in violation of G.L. c. 93A. Defendants offered no settlement of Plaintiff's claims.

194. At all relevant times hereto, Defendants were engaged in trade or commerce within the Commonwealth of Massachusetts and the acts and omissions that affected Mrs. Dorsey were performed primarily and substantially within the Commonwealth of Massachusetts.

195. Defendants' actions described herein were performed willfully and knowingly.

196. As a result of Defendants' unfair and deceptive conduct, Plaintiff sustained injuries, including but not limited to, physical and emotional harm and unnecessary costs and expenses, including attorney's fees, associated with filing this action.

197. Plaintiff is entitled to be compensated for all harm sustained by her and to all damages allowed by law, including at least double, and not less than treble, damages, costs, interest and attorney's fees.

COUNT II
(Mrs. Dorsey v. All Defendants)
(Strict Product Liability)

198. The preceding paragraphs of this Complaint are realleged and incorporated by reference as if fully set forth herein.

199. Defendants manufactured and sold Neurontin despite the fact that a defect or unreasonably dangerous condition existed at the time Neurontin left the Defendants' hands.

200. At the time Neurontin was sold by Defendants it was not reasonably suitable for the ordinary uses for which goods of that kind were marketed and sold.

201. At the time of Plaintiff's injury, she was using Neurontin in a manner that the Defendants intended or that could reasonably have been foreseen by the Defendants.

202. The defect or unreasonably defective condition prevalent in Neurontin at the time it was sold to Plaintiff was the legal cause of her injuries and Plaintiff is entitled to be compensated for same to the full extent that the law provides.

COUNT III
(Mrs. Dorsey v. All Defendants)
(Strict Product Liability – Failure to Warn and False Advertising)

203. Plaintiff incorporates all preceding paragraphs as fully set forth herein, and further alleges as follows.

204. Defendants and/or their predecessors manufacture and/or supply Neurontin.

205. The Neurontin manufactured and/or supplied by Defendants was accompanied by false advertising regarding its appropriate uses and was unaccompanied by proper warnings regarding all possible side effects associated with the use of

Neurontin and the comparative severity, incidence, and duration of such adverse effects, i.e., the warnings given did not accurately reflect the signs, symptoms, incidence, scope or severity of the side effects.

206. Defendants or their predecessors created false statements regarding Neurontin, and failed to perform adequate testing that would have shown that Neurontin possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting the symptoms, scope and severity should have been made, both with respect to the use of this drug.

207. The Neurontin manufactured and/or supplied by Defendants was defective because it was proscribed at Defendants' behest for unapproved uses and due to inadequate warnings or instructions. The manufacturer knew or should have known of the risk of injury from Neurontin, and it failed to provide adequate warnings to users or consumers of the Product and continued to aggressively promote Neurontin.

208. As a producing cause and legal result of the defective condition of Neurontin, as manufactured and/or supplied by Defendants, and as a direct and legal result of negligence, carelessness, or other wrongdoing and actions of the Defendants described herein, Plaintiff suffered, and will continue to suffer injury, harm and economic loss.

209. Based upon information and belief, Defendants knew of Neurontin's defective nature but continued to design, manufacture, market and sell Neurontin so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Neurontin.

210. Defendants' conduct in the license, design, manufacturing, assembly, packing, warning, marketing, advertising, promotion, distribution and sale of Neurontin, was fraudulent, knowing misconduct, and/or conduct undertaken recklessly and with conscious disregard for the safety of consumers such as Plaintiff, such as to constitute despicable conduct, and oppression, fraud and malice, and such conduct was at all times ratified by the corporate Defendants herein, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial.

COUNT IV
(Mrs. Dorsey v. All Defendants)
(Strict Product Liability – Defective Design/Manufacturing)

211. Plaintiff incorporates all preceding paragraphs as fully set forth herein and further alleges as follows.

212. Defendants or their predecessors are manufacturer and/or supply Neurontin.

213. The Neurontin manufactured and/or supplied by the corporate Defendants was placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition in that the foreseeable risk exceeded the benefit associated with the design or formulation.

214. Alternatively, Neurontin, as manufactured and/or supplied by Defendants, was defective in design or formulation in that when such drug was placed in the stream of commerce, it was unreasonably dangerous, was more dangerous than an ordinary consumer would expect and more dangerous than other forms of treatment for Bipolar Disorder.

215. Based upon information and belief, Defendants knew of Neurontin's defective nature but continued to design, manufacture, market and sell Neurontin so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Neurontin.

216. As a producing cause and legal result of the defective and unreasonably dangerous condition of Neurontin, as manufactured and/or supplied by Defendants, and as a direct and proximate result of the negligence, carelessness or the wrongdoing and action(s) of Defendants described herein, Plaintiff suffered, and will continue to suffer injury, harm and economic loss.

217. Defendants' conduct in the license, design, manufacturing, assembly, packing, warning, marketing, advertising, promotion, distribution and sale of Neurontin, was fraudulent, knowing misconduct, and/or conduct undertaken recklessly and with conscious disregard for the safety of consumers such as Plaintiff, such as to constitute despicable conduct, and oppression, fraud and malice, and such conduct was at all times ratified by the corporate Defendants herein, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial.

COUNT V
(Mrs. Dorsey v. All Defendants)
(Breach of Express Warranty)

218. Plaintiff incorporates all preceding paragraphs as fully set forth herein and further alleges as follows.

219. Defendants expressly warranted that Neurontin was safe and well-accepted by patient studies.

220. Neurontin does not conform to these express representations because Neurontin is not safe and was never approved for many of the conditions for which it was marketed, including Bipolar Disorder.

221. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer injury, harm, and economic loss.

COUNT VI
(Mrs. Dorsey v. All Defendants)
(Breach of Implied Warranty)

222. Plaintiff incorporates all preceding paragraphs as fully set forth herein and further alleges as follows.

223. At the time Defendants marketed, sold, and distributed Neurontin for use by Plaintiff, Defendants knew of the use for which Neurontin was intended and impliedly warranted the Product to be of merchantable quality and safe and fit for its intended use.

224. Plaintiff and her physicians reasonably relied upon the skill and judgment of Defendants as to whether Neurontin was of merchantable quality and safe and fit for its intended use.

223. Contrary to such implied warranty, Neurontin was not of merchantable quality or safe or fit for its intended use because Neurontin was, and is, unreasonably dangerous and unfit for the ordinary purpose for which it was used, as described above.

224. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff has suffered, and will continue to suffer, injury, harm, and economic loss.

COUNT VII
(Mrs. Dorsey v. All Defendants)
(Fraud, Misrepresentation and Deceit)

225. The preceding paragraphs of this Complaint are realleged and incorporated by reference as if fully set forth herein.

226. Defendants made false representations of material fact to Plaintiff and the general public in an effort to induce Plaintiff to act on those representations; including false and deceptive statements set forth above regarding the promotion and marketing of Neurontin.

227. Defendants made their misrepresentations intending to induce Plaintiff to rely thereon and to use Neurontin.

228. Plaintiff reasonably relied on these misrepresentations to her detriment and has been harmed by these misrepresentations. Plaintiff is entitled to be compensated for all harm caused by these misrepresentations.

COUNT VIII
(Mrs. Dorsey v. All Defendants)
(Negligence)

229. The preceding paragraphs of this Complaint are realleged and incorporated by reference as if fully set forth herein.

230. Defendants owed a duty to Plaintiff and all of its consumers to abide by federal law regarding the promotion and marketing of Neurontin and to provide safe products to the consuming public.

231. Defendants breached their duty of care to Plaintiff by the actions set forth in this Complaint.

232. Defendants' breaches of duty proximately caused Plaintiff's physical harm, emotional distress and economic damages and Plaintiff is entitled to be compensated for that harm.

COUNT IX
(Mrs. Dorsey v. All Defendants)
(Unjust Enrichment)

233. The preceding paragraphs of this Complaint are realleged and incorporated by reference as if fully set forth herein.

234. By their wrongful acts described above, Defendants have been unjustly enriched to the detriment of Plaintiff, including but not limited to being unjustly enriched by the wrongful profits earned on illegal Nuerontin sales.

235. By reason of the foregoing, Plaintiff has suffered damages for which Defendants are legally responsible and Plaintiff is entitled to be compensated for same in an amount to be determined at trial.

COUNT X
(Mrs. Dorsey v. All Defendants)
(Intentional Infliction of Emotional Distress)

236. The preceding paragraphs of this Complaint are realleged and incorporated by reference as if fully set forth herein.

237. By their actions described herein, Defendants intended to inflict emotional distress upon Mrs. Dorsey or knew or should have known that emotional distress was the likely result of their conduct.

238. Defendants' conduct was extreme and outrageous, beyond all possible bounds of decency and utterly intolerable in a civilized community.

239. Defendants' actions caused Plaintiff to suffer extreme and severe emotional distress.

240. Plaintiff is entitled to recover damages for all harm caused by Defendants' actions.

COUNT XI
(Mrs. Dorsey v. All Defendants)
(Loss of Consortium)

241. The preceding paragraphs of this Complaint are realleged and incorporated by reference as if fully set forth herein.

242. By the acts alleged in this Complaint, Defendants proximately caused a loss of consortium between Mrs. Dorsey and her husband, including a loss of care, society, and companionship.

243. Defendants are liable for all harm caused by the above-stated loss of consortium.

COUNT XII
(Estate of James Dorsey v. All Defendants)
(Loss of Consortium)

244. The preceding paragraphs of this Complaint are realleged and incorporated by reference as if fully set forth herein.

245. By the acts alleged in this Complaint, Defendants proximately caused a loss of consortium between James Dorsey and his wife, including a loss of care, society, and companionship.

246. Defendants are liable for all harm caused by the above-stated loss of consortium.

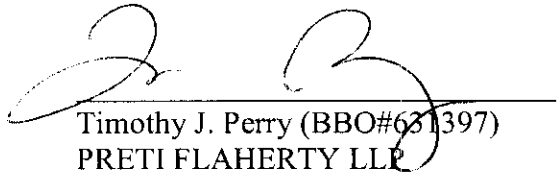
VII. Jury Demand

Plaintiff demands a trial by jury on all counts of the Complaint to which she is entitled to a jury trial.

Respectfully submitted,

MARY P. DORSEY,

By her attorney,



Timothy J. Perry (BBO#631397)
PRETI FLAHERTY LLP
114 State Street, Suite 200
Boston, MA 02109
(617) 742-9012
fax (617) 742-9013

Dated: April 1, 2005

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. TITLE OF CASE (NAME OF FIRST PARTY ON EACH SIDE ONLY) Mary P. Dorsey v. Pfizer, Inc.

2. CATEGORY IN WHICH THE CASE BELONGS BASED UPON THE NUMBERED NATURE OF SUIT CODE LISTED ON THE CIVIL COVER SHEET. (SEE LOCAL RULE 40.1(A)(1)).

_____ I. 160, 410, 470, R.23, REGARDLESS OF NATURE OF SUIT.

_____ II. 195, 368, 400, 440, 441, 444 540, 550, 555, 625, 710,720,730 740, 790, 791, 820*, 830*, 840*, 850, 890, 892, 894, 895, 950. *Also complete AO 120 of AO 121 for patent, trademark or copyright cases

X III. 110, 120, 130, 140, 151, 190, 210, 230, 240, 245, 290, 310 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 370, 371 380, 385, 450, 891.

05 10639 RCL

_____ IV. 220, 422, 423, 430, 460, 510, 530, 610, 620, 630, 640, 650, 660, 690, 810, 861, 865, 870, 871, 875, 900.

_____ V. 150, 152, 153.

3. TITLE AND NUMBER, IF ANY, OF RELATED CASES. (SEE LOCAL RULE 40.1(G)). IF MORE THAN ONE PRIOR RELATED CASE HAS BEEN FILED IN THIS DISTRICT PLEASE INDICATE THE TITLE AND NUMBER OF THE FIRST FILED CASE IN THIS COURT.

N/A

4. HAS A PRIOR ACTION BETWEEN THE SAME PARTIES AND BASED ON THE SAME CLAIM EVER BEEN FILED IN THIS COURT?

YES (NO)

5. DOES THE COMPLAINT IN THIS CASE QUESTION THE CONSTITUTIONALITY OF AN ACT OF CONGRESS AFFECTING THE PUBLIC INTEREST? (SEE 28 USC §2403

YES (NO)

IF SO, IS THE U.S.A. OR AN OFFICER, AGENT OR EMPLOYEE OF THE U.S. A PARTY?

YES NO

6. IS THIS CASE REQUIRED TO BE HEARD AND DETERMINED BY A DISTRICT COURT OF THREE JUDGES PURSUANT TO TITLE 28 USC §2284?

YES (NO)

7. DO ALL OF THE PARTIES IN THIS ACTION, EXCLUDING GOVERNMENTAL AGENCIES OF THE UNITED STATES AND THE COMMONWEALTH OF MASSACHUSETTS ("GOVERNMENTAL AGENCIES"), RESIDING IN MASSACHUSETTS RESIDE IN THE SAME DIVISION? – (SEE LOCAL RULE 40.1(D)).

(YES) NO

A. IF ~~YES, IN~~ WHICH DIVISION DO ALL OF THE NON-GOVERNMENTAL PARTIES RESIDE?

(EASTERN DIVISION) CENTRAL DIVISION WESTERN DIVISION

B. IF NO, IN WHICH DIVISION DO THE MAJORITY OF THE PLAINTIFFS OR THE ONLY PARTIES, EXCLUDING GOVERNMENTAL AGENCIES, RESIDING IN MASSACHUSETTS RESIDE?

EASTERN DIVISION CENTRAL DIVISION WESTERN DIVISION

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME Timothy J. Perry

ADDRESS Preti Flaherty LLP, 114 State Street, Boston, MA 02109

TELEPHONE NO. (617)742-9012

JS 44
(Rev 3/99)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information co ied herein neither replace nor supplement the filir d service of pleadings of other papers as required by law, except as provided by local rules of court. his form, approved by the Judicial Conference of the ed States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I (a) PLAINTIFFS

MARY P. DORSEY

DEFENDANTS

Pfizer, Inc.
Warner Lambert Company
Parke-Davis

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF (EXCEPT IN U.S.PLAINTIFF CASES) ~~Barnstable~~

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT (IN U.S.PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER

Timothy J. Perry (617)742-9012
Preti Flaherty LLP
114 State Street, Boston, MA 02109

ATTORNEYS (IF KNOWN)

David B. Chaffin
Hare & Chaffin
160 Federal Street, Boston, MA 02110

05 10639 RCL

II. BASIS OF JURISDICTION (PLACE AN "X" IN ONE BOX ONLY)

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN "X" IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated or Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Lands (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholder's Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tot Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury-Med Malpractice
- ☒ 365 Personal Injury-Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth In Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentences

HABEAS CORPUS
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patents
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statute
- ☐ 890 Other Statutory Actions

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION (CITE THE U.S.CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY.)

Products liability for improper drug marketing. Diversity jurisdiction pursuant to 28 U.S.C. 1332.

VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION ☐ UNDER F.R.C.P. 23 **DEMAND** $3,000,000 CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ YES ☐ NO

VIII. RELATED CASE(S) IF ANY (See Instructions): JUDGE _____ DOCKET NUMBER _____

DATE 3/30/05 4/1/05 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 05 10639 RCL

MARY P. DORSEY, Individually and as Administrator of the Estate of James Dorsey

Plaintiff,

v.

PFIZER, INC., WARNER LAMBERT COMPANY, and PARKE-DAVIS, a division of Warner-Lambert Company,

Defendants.

RECEIPT # 63108
AMOUNT $ 250.00
SUMMONS ISSUED 3
LOCAL RULE 4.1 /
WAIVER FORM /
MCF ISSUED /
BY DPTY. CLK. M.P.
DATE 4/1/05

MAGISTRATE JUDGE New Mag. Judge

COMPLAINT

For her complaint against the named defendants, Plaintiff Mary P. Dorsey states as follows:

I. Introduction

Plaintiff is one of many victims of the historic and criminal consumer fraud scam undertaken by the Defendant pharmaceutical makers. On or about May 13, 2004, Defendant Warner Lambert Company admitted guilt to a criminal Information filed by the United States Attorney in Boston charging it with distribution of the drug Neurontin for unapproved uses and as a misbranded drug. One of the unapproved uses for which the drug was marketed was bipolar disorder. As a result, Plaintiff, who was prescribed Neurontin for treatment of a bipolar disorder, had catastrophic reactions to the drug. Among other things, she experienced a year long drug-induced stupor which, tragically, coincided with her husband's diagnosis with, struggle against, and eventual death from

malignant melanoma. Plaintiff seeks all damages to which she is entitled for Defendant's crimes and the state law causes of action set forth herein.

II. Parties

1. Plaintiff Mary P. Dorsey ("Plaintiff" or "Mrs. Dorsey") is an individual residing in the Commonwealth of Massachusetts. Plaintiff is the Administrator of the Estate of her late husband, James Dorsey.

2. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with a principal place of business in New York, New York with a registered agent in Boston, Massachusetts

3. Defendant Warner Lambert Company ("Warner-Lambert") is a Delaware corporation with a principal place of business in New Jersey with a registered agent in Boston, Massachusetts.

4. Defendant Parke Davis & Company ("Parke Davis") is a Michigan corporation with a principal place of business in Detroit, Michigan with a registered agent in Boston, Massachusetts.

III. Jurisdiction and Venue

5. This Court has diversity jurisdiction over this matter pursuant to 28 U.S.C. § 1332.

6. This Court has personal jurisdiction over the parties because Plaintiff is a resident of the Commonwealth of Massachusetts and Defendants conduct business within the Commonwealth of Massachusetts and the actions and omissions regarding Plaintiff occurred primarily and substantially within the Commonwealth of Massachusetts.

7. Venue is proper in this Court became Plaintiff resides in this judicial district and Defendants conduct business in this judicial district.

IV. Facts Common to All Counts

A. Neurontin and the Statutory Requirements for New Drugs

8. Pfizer is principally engaged in the manufacture and sale of pharmaceutical products. Upon information and belief, Pfizer acquired Warner-Lambert Company ("Warner-Lambert") in or around the year 2000. Upon information and belief, this acquisition included Warner-Lambert's Parke-Davis division. Pfizer is, therefore, responsible for all liabilities which result from any acts or omissions of Parke-Davis or Warner Lambert. At times throughout this Complaint, Parke-Davis, Warner-Lambert and Pfizer may be referred to collectively as "Defendants."

9. As detailed in this Complaint, Pfizer currently markets and sells the drug known as Neurontin. Prior to Pfizer's acquisition of Warner-Lambert, Neurontin was marketed and sold by Parke-Davis, a division of Warner-Lambert.

10. Warner-Lambert's Parke Davis Division was engaged in, among other things, the development, manufacture, promotion, sale and interstate distribution of prescription drugs intended for human use within the United States. Warner-Lambert's pharmaceutical manufacturing facilities were located in Puerto Rico, from which it shipped products to all fifty states and the District of Columbia.

11. The Federal Food, Drug and Cosmetic Act ("FDCA"), among other things governs the lawful interstate distribution of drugs for human use. As codified at Title 21, United States Code, Sections 331 et seq., and specifically at § 355(b), the

FDCA, and its implementing regulations, require that before a new drug may legally be distributed in interstate commerce, a sponsor of a new drug product must submit a New Drug Application ("NDA").

12. The FDCA required, at 21 U.S.C. § 355, that the NDA sponsor submit to the United States Food and Drug Administration ("FDA"), as part of an NDA, proposed labeling for the proposed intended uses for the drug, which included, among other things, the conditions for therapeutic use. The NDA must also provide, to the satisfaction of FDA, data generated in randomized and well-controlled clinical trials that demonstrates that the drug will be safe and effective when used in accordance with the proposed labeling.

13. The FDCA, at 21 U.S.C. § 355, prohibits the introduction into interstate commerce of any new drug, unless an approval of an NDA is effective. Only after the NDA, including the proposed labeling, is reviewed and approved by FDA, is the sponsor permitted by law to promote and market the drug, and only for the medical conditions of uses specified in the approved labeling, for which uses FDA had found sufficient evidence of safety and effectiveness. Uses unapproved by FDA, not included in the drug's labeling, are known as "unapproved uses" or "off-label uses."

14. The FDCA, and the regulations promulgated thereunder, required that in order to label or promote a drug for a use different than the conditions for use specified in the approved labeling, the sponsor had to file a new NDA, or amend the existing NDA, by, among other requirements, submitting the newly proposed indications for use and evidence, in the form of randomized and well-controlled clinical studies, sufficient to demonstrate that the drug would be safe and effective for the newly proposed therapeutic

use or uses. Only upon approval of the new NDA could the sponsor promote the drug for the new intended use.

15. The FDCA, at 21 U.S.C. § 352(f)(1), provided that a drug was misbranded if, among other things, the labeling did not contain adequate directions for use. As the phrase is used in the FDCA, adequate directions for use cannot be written for medical indications or uses for which the drug had not been proven to be safe and effective through well-controlled clinical studies because that would be misleading under Section 352(a).

16. The FDCA, 21 U.S.C. § § 331(a)(d), 333(a), and 355, prohibits the distribution in interstate commerce of an unapproved new drug or of a misbranded drug.

17. In or about 1993, Warner-Lambert submitted an NDA for approval of a drug called Neurontin (also known by the chemical name gabapentin), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R. § 310.3 (h)(4) and (5). In that application, Warner-Lambert sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of seizures with and without secondary generalization in adults with epilepsy.

18. On or about December 30, 1993, FDA approved Neurontin for that specific use only. This approved use for Neurontin will be referred to throughout this Complaint as the "approved use."

19. Because Warner-Lambert had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than the approved use.

20. Further, Neurontin was not, pursuant to 21 U.S.C. § 355(i), exempt from the prohibition of introducing into interstate commerce a new drug for medical indications beyond the conditions prescribed, recommended, or suggested in the approved labeling thereof.

21. From at least June of 1995 through at least August 20, 1996, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD); and migraine headaches, among other uses. These and other unapproved uses for Neurontin will be collectively referred to in this Complaint as the "unapproved uses."

22. Warner-Lambert did not file a new NDA seeking FDA approval for any of these unapproved uses during the time period addressed in a Criminal Information brought against Warner-Lambert by the United States Attorney on or about May 13, 2004 (the "Information"). Of these unapproved uses, only post-herpetic neuralgia has ever received FDA approval, and that approval was applied for and received after the events described in the Complaint.

B. Plaintiff's Personal Background

23. Plaintiff was born November 29, 1941 in Clinton, Massachusetts. Plaintiff has resided in Massachusetts all her life. After completing high school, Plaintiff attended, and graduated from, the Chandler School for Women in Boston, Massachusetts. Following her graduation she was employed by Mitre Corporation in Bedford, Massachusetts.

24. Plaintiff married James Dorsey ("Mr. Dorsey") on May 15, 1965. At that time, Plaintiff resigned from her job at Mitre to begin a family. Plaintiff gave birth to four children between May of 1966 and 1970. Plaintiff now has four grandchildren.

25. Plaintiff acquired her real estate broker's license in 1976. Plaintiff was employed by the Victor Company (a real estate firm) in Andover, Massachusetts from approximately 1977 to June of 1997.

26. In June 1997, Plaintiff suffered a stroke. Plaintiff was diagnosed with partial paralysis of the left side, speech problems, long and short-term memory loss, and math skills that had diminished to a fifth grade level. After her stroke, Plaintiff was unable to continue work as a broker.

C. Plaintiff is Prescribed Neurontin For Unapproved Uses

27. Following her stroke in June of 1997, Plaintiff suffered from, among other things, bipolar disorder. It was also initially believed by Plaintiff's physicians that she was experiencing non-epileptic seizures. To address these problems, Plaintiff was prescribed Neurontin because, based on Defendants' marketing of the drug, her physicians believed Neurontin was appropriate for her disorders.

28. Neurontin, however, had never been approved by the FDA for these uses.

29. Plaintiff was initially prescribed Neurontin by Dr. Jonathan Alpert in or about 1999.

30. After beginning on Neurontin, Plaintiff's condition worsened. Plaintiff experienced more, rather than less, seizure-like symptoms and had thoughts of suicide. She was constantly lethargic and often experienced "black-outs." Due to her worsening

condition, Plaintiff was advised not to drive and was constantly concerned with the possibility of another seizure and what the consequences of that might be.

31. In or about 2003, Plaintiff "blacked-out" while in her psychologist's office and had to be taken to the hospital by ambulance.

32. Plaintiff's worsening medical condition coupled with her constant living in fear led her to suffer from severe anxiety and depression as well as sleep and appetite disturbances.

33. In fact, Plaintiff's husband and Plaintiff's other family members recall that during the period in which she used Neurontin she was "like a zombie." This physical and emotional state led to an extreme loss of care, comfort, support and companionship with her husband, children, grandchildren and friends.

34. Tragically, in June of 2002, during the height of the period in which she was affected by Neurontin, Plaintiff's husband was diagnosed with malignant melanoma cancer and given a little more than a year to live.

35. Shortly thereafter, in September of 2002, Plaintiff suffered a second stroke.

36. The Plaintiff continued to suffer from severe anxiety, depression, and seizures, and for nearly one year after her husband's diagnosis was unable to provide him with any meaningful care in what proved to be the final year and a half of his life.

37. In fact, Plaintiff's husband witnessed her suffer seizure-like symptoms on more than one occasion while he was ill and at one point had to go to the hospital to feed the Plaintiff.

38. In or about 2003, Plaintiff consulted a neurologist who confirmed that Plaintiff had never, in fact, had seizures prior to taking Neurontin and that she was "over-medicated." This physician ordered Plaintiff to be taken off Neurontin. Plaintiff was weaned off the drug entirely by July of 2003.

39. Within one month of ceasing the Neurontin prescription, Plaintiff underwent a complete turnaround in her condition. She no longer suffers from any seizures and both her family and her treating physicians are stunned by her progress.

D. Defendants' Deceptions Caused the Unapproved Use Prescriptions

40. In December 1993, the FDA approved Neurontin as "adjunctive therapy" for the treatment of certain types of seizures in adult patients *suffering from epilepsy*. "Adjunctive therapy" means that the drug could not be prescribed by itself for the treatment of epilepsy, but as an add-on drug in the event that a primary anti-epilepsy drug was not successful.

41. The FDA-approved labeling of Neurontin stated that the drug was only effective at 900 to 1800 mg/day.

42. At the time Neurontin was approved, Park-Davis' original patent on Neurontin was set to expire in December 1998.

43. In October 1990, Parke-Davis filed a patent for Neurontin claiming it to be effective in the treatment of depression. In November 1990, Parke-Davis filed another patent application for Neurontin claiming it to be effective for the treatment of neurogenerative disease.

44. In 1995, additional patent applications were filed by Parke-Davis for mania and bipolar disease and for anxiety and panic.

45. Notwithstanding the claims made in its patent applications, neither Parke-Davis, Warner-Lambert or Pfizer ever sought FDA approval for the use of Neurontin to treat the conditions described in the four patent applications referenced above.

46. Upon information and belief, there are two million epileptics in the United States. Upon information and belief, because Defendants did not consider this to be a large market for Neurontin, Defendants sought to illegally promote Neurontin for unapproved and unsafe uses.

47. From in or about June of 1995 through in or about August 20, 1996, by certain of the conduct described in greater detail below, Warner-Lambert promoted the sale and use of Neurontin for certain conditions other than for its approved use in Massachusetts and elsewhere.

48. In or about the fall of 1995, Warner-Lambert's Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including conference calls on pain and a pain consultants meeting.

49. Upon information and belief, certain of Parke-Davis' annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies and tactics for increasing sales for "off-label" uses of the drug. The marketing plans budgeted for and funded these tactics.

50. In or about April and May of 1995, Warner-Lambert performed a marketing assessment of proposed psychiatric indications for Neurontin. In that marketing assessment, Warner-Lambert forecast potential revenue from Neurontin for

bipolar and anxiety treatment under two scenarios: with and without FDA approval. Warner-Lambert's Neurontin development team and new product committee reviewed the potential psychiatric uses and concluded that the company would not seek approval to promote and sell the drug for these unapproved uses.

51. One of the principal factors Warner-Lambert considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that Warner-Lambert had been developing. The company expected this new drug would be approved by FDA not only for epilepsy but also for a variety of uses beyond Neurontin's approved use.

52. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in Warner-Lambert's original NDA approval for Neurontin. If Warner-Lambert sought and obtained approval for any of the unapproved uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those unapproved uses. Upon information and belief, Warner-Lambert was concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

53. Upon information and belief, Defendants' sales departments recognized a significant profit potential in the promotion of Neurontin for unapproved uses.

54. From early 1995, on repeated occasions, Warner-Lambert determined not to seek FDA approval for certain unapproved uses.

55. In or about July of 1995, Warner-Lambert's assessment of Neurontin's market potential for neuropathic pain was distributed to its Neurontin Development Team and to a Warner-Lambert Vice-President for Marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to the FDA for approval.

56. Upon information and belief, after performing an extensive economic analysis, senior officials at Parke-Davis determined that it was not sufficiently profitable for Parke-Davis to obtain FDA approval for Neurontin's alternative uses.

57. Instead, Parke-Davis officials developed a strategy that would allow Parke-Davis to avoid the costs of proving that Neurontin was safe and effective for these other uses, while allowing Parke-Davis to compete in the lucrative markets for unapproved uses.

58. Upon information and belief, a group of Parke-Davis executives called the "New Products Committee" approved an alternative strategy – in other words a strategy to generate these additional uses of Neurontin without getting FDA approval.

59. The head of the New Products Committee was the then-president of the company, Tony Wild.

60. Upon information and belief, an internal memo, dated May 5, 1997, and written on Parke-Davis stationery, poses the central question: "Did it make sense for Parke-Davis to do rigorous and expensive clinical trials to prove to the FDA that Neurontin worked for the burning, tingling pain of diabetic neuropathy?"

61. Upon information and belief, the memo's response was: "It did not."

62. According to the May 5, 1997 memo, there was a study that showed Neurontin worked better than a placebo, but, upon information and belief, Parke-Davis recognized that more studies were needed.

63. Upon information and belief, Warner-Lambert's epilepsy marketing team recommended that Parke-Davis skip the studies and promote Neurontin for pain directly to doctors in meetings and through educational seminars.

64. Upon information and belief, In October 1995, a member of Warner-Lambert's epilepsy disease team circulated a memorandum to a group including other senior members of Warner-Lambert's epilepsy disease team noting that data purchased from an outside vendor showed that physicians had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 Warner Lambert sales representatives for whom data was available in a two month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

65. On or about July 10, 1996, a Park-Davis sales representative met with a physician in Monroe, Louisiana, and detailed the physician on Neurontin for the treatment of pain.

66. Also in 1996, a sales representative created a document that stated that sales representatives could ask physicians during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales representatives could do lunch programs on Neurontin

and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

67. Upon information and belief, tens of thousands of bipolar disorder patients ended up being treated "off-label" with Neurontin. Plaintiff was one of these victims.

68. Despite Parke-Davis' representations, a scientifically valid study conducted at the Harvard Bipolar Research Program found that patients did *worse* on Neurontin than those who were on a sugar pill.

69. Indeed, Parke-Davis sponsored this 1998 study and, therefore, was aware of the results. Parke-Davis failed to publish the results, however, until two years later.

70. By that time, upon information and belief, Neurontin accounted for $1.3 billion in sales, with over 80% of its use coming from non-approved uses, such as the treatment of bipolar disorder.

71. The Warner-Lambert unapproved use scheme was carried out by employing, upon information and belief, the following strategies, among others:

a. illegal kickbacks to physicians who prescribed large amounts of Neurontin for unapproved purposes to patients whose prescriptions were paid for by Medicare or Medicaid;
b. the formation of a nationwide network of employees falsely referred to as "medical liaisons" whose actual assigned duties consisted entirely of conventional direct sales activities and which did not include any legitimate scientific activity;
c. the illegal direct solicitation of physicians for "off- label" uses;
d. the making of false statements to physicians and pharmacists concerning the efficacy and safety of Neurontin for unapproved uses;
e. the making of such false statements directly to the Veterans Administration concerning the safety and efficacy of Neurontin for unapproved uses;
f. the charging of full price for drugs actually being used in experimental trials and thus subject to federal price restriction;
g. the systematic avoidance of filing requirements with the FDA;

h. the deliberate avoidance of the FDA's classification of Neurontin as to its therapeutic equivalency and thus the avoidance of Medicare and Medicaid price limitations based on therapeutic equivalency;
i. the use of active concealment to avoid the FDA's enforcement mechanisms and the resultant mandatory interruption of medicare and medicaid payments for Neurontin prescriptions;
j. the use of active concealment to avoid the "formulary" policies of various state agencies administering Medicare and Medicaid programs which are intended to refuse payment for uses of drugs which are not medically recognized as statutorily defined;
k. the payment or offering of gratuities to Parke-Davis employees in order to procure their silence; and
l. the active training of Parke-Davis employees in methods of avoiding detection of their activities by the FDA.

E. Defendants' Kickback Schemes

1. Consultants' Meetings

72. Upon information and belief, Warner-Lambert used so-called "consultant meetings" to funnel illegal payments to physicians to encourage them to prescribe Neurontin for unapproved uses.

73. Warner-Lambert paid physicians to attend dinners and conferences and paid them to hear presentations about the unapproved uses of Neurontin.

74. Under the fiction that these physicians were acting as consultants, Warner-Lambert sometimes (but not always) had the physicians sign sham consulting agreements.

75. At these meetings, Warner-Lambert provided the physicians with lengthy presentations relating to Neurontin, particularly regarding unapproved uses.

76. Presentations would be made by Warner-Lambert employees or physician speakers hired by Warner-Lambert for the purpose of promoting Neurontin, and

attendees' questions relating to the administration of Neurontin use would be solicited and answered.

77. Upon information and belief, the sponsoring organization or Warner-Lambert often intentionally posed questions to the speakers about unapproved uses to insure that the attendees were exposed to such information.

78. Despite its pretensions, the consultants' meetings were not held (and the "consultants" were not paid) for the purpose of providing Warner-Lambert with expert, independent advice.

79. Upon information and belief, Warner-Lambert generally did not even record the "advice" provided by its "consultants" and certainly did not act upon it.

80. Upon information and belief, Warner-Lambert did, however, routinely analyze whether the "consultants" meetings were successful in getting the attendees to change their prescription writing practices. Upon information and belief, at some meetings, the "consultants" were directly asked if they would write more Neurontin prescriptions as a result of the meeting.

81. Warner-Lambert also routinely tracked consultants' Neurontin prescription writing practices after these meetings.

82. Upon information and belief, using market data purchased from third parties, Warner-Lambert analyzed whether the physicians they had paid had written more Neurontin prescriptions after the meeting.

83. Warner-Lambert organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida on April 19-21, 1996. Approximately 42 physicians

attended the meeting, including nine physicians who made presentations relating to unapproved uses of Neurontin.

84. Upon information and belief, Warner-Lambert invited certain physicians to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, Warner-Lambert paid for accommodations and meals for the invited physicians and their spouse or guest, and paid an honorarium to each of the physician attendees. Physicians who acted as faculty were paid between $ 1,500 and $ 2,000.

85. In a memorandum announcing the event to Warner-Lambert personnel, the Neurontin Marketing Team acknowledged that in order to target neurologists with the greatest potential for writing Neurontin prescriptions, sales personnel must select potential attendees from a list of the top prescription writers for anti-epileptic drugs in the Northeast; only persons who fell within this desirable demographic were allowed to be invited.

86. Upon information and belief, qualifying physicians were given round-trip airfare to Florida (worth approximately $800.00), two nights accommodations (worth approximately $340.00), free meals and entertainment, ground transportation and a "consultant's fee" of approximately $250.00.

87. Ample time was provided so that the Warner-Lambert "consultants'" could enjoy the beach resort.

88. Upon information and belief, the value of the junket was approximately $2,000.00 per physician.

89. Upon information and belief, the Jupiter Beach "consultants'" meeting included two half days of presentations by Warner-Lambert relating to Neurontin, including extensive presentations relating to "off- label" uses.

90. All aspects of the presentation were designed, monitored, and approved by Warner-Lambert.

91. Among the presentations made to the physicians in attendance was one relating to off label uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment for pain.

92. Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol and pain.

93. On or about May 8, 1996, following the Jupiter Beach conference, Warner-Lambert circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations. Warner-Lambert told its employees that: "[t]he meeting was a great success and the participants were delivered a hard-hitting message about Neurontin." Upon information and belief, Warner-Lambert distributed to these employees a form entitled "Jupiter Beach Trending Worksheet" which was intended to be used to gauge the effect of the meeting on the prescribing by doctors who attended the Jupiter Beach meeting.

94. These worksheets enabled Warner-Lambert to track Neurontin prescription habits of the attendees before and after the "consultants'" meetings to determine if these "high writing" prescribers wrote more Neurontin scripts after the conference. Persuading these heavy prescribers to order more Neurontin for their patients was, upon information and belief, the sole purpose of the Jupiter Beach junket.

95. Jupiter Beach was not unique. Warner-Lambert hosted dozens of "consultants" meetings between late 1995 and 1997 in which the "consultants" received payments and gratuities as well as presentations on unapproved uses for Neurontin designed, upon information and belief, to change the physicians' prescription writing habits.

96. From August 1-5, 1996, Warner-Lambert organized an "advisory board meeting," in Atlanta, Georgia in conjunction with the 1996 Summer Olympics. Warner-Lambert expressly instructed several of the physician speakers to address some of the off label uses.

97. During this meeting, Warner-Lambert hosted physicians at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. The company had already had numerous opportunities to consult with physicians and, in fact, many of them had spoken on Warner-Lambert's behalf at prior meetings. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations. Comparable consultants' meetings included, but were not limited to the following:

Mastering Epilepsy, La Costa Resort, CA July 20-23, 1995
Mastering Epilepsy, Santa Fe, NM November 16-19, 1995

Neurontin Consultants Conference, Marco Island, FL February 2-4, 1996
Pediatric Epilepsy, Hutchinson Island, FL February 9-11, 1996
Mastering Epilepsy Science, Walt Disney World, FL February 22-25, 1996
Pediatric Epilepsy, Hutchinson Island, FL March 8-10, 1996
Mastering Epilepsy, Ritz Carlton, Aspen, CO April 18-21, 1996
Affective Disorders in Psychiatry, Marco Island, FL April 20, 1996
Affective Disorder Consultants Conference, Southern Pines, NC April 27, 1996
Neuropathic Pain Conference, Palm Beach, FL May 11, 1996
Epilepsy Management, Rancho Bernardo, CA June 28-30, 1996
Use of Anti-Convulsants in Psychiatric Disorders, Short Hills, NJ October 18-19, 1996
Non-epileptic Uses of Neurontin, Longboat Key, FL November 6, 1996
Neurological Conditions Conference, Ritz Carlton, Atlanta, GA September 27-28, 1997

98. Other "consultants'" meetings took place at Charleston, SC, Coconut Grove, FL, Naples, FL, Memphis, TN, Louisville, KY, Washington, D.C., Aspen, CO, and other places. Hundreds, if not thousands, of physicians received kickbacks to attend these events.

99. Not all payments to "consultants" were made at conferences as elaborate as Jupiter Beach or Atlanta.

100. Many "consultants'" meetings consisted of lavish dinners at local restaurants.

101. Upon information and belief, the emphasis on these meetings was also on unapproved uses, and $200 "honorariums" were paid to the physicians who did nothing for the payment except show up.

102. Upon information and belief, at none of the events did the "consultants" did not provide legitimate consultation to Warner-Lambert at these meetings, but rather were encouraged to increase their Neurontin prescription writing.